

REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 62-81 are pending in the present application, including independent claim 62. Independent claim 62, for instance, is directed to a method for detecting the presence of a metalloproteinase in a chronic wound of a human or an animal. The method comprises collecting a sample of fluid from the chronic wound and exposing the sample to a target antibody that is configured to bind with the metalloproteinase to form a target antibody/metalloproteinase complex. The metalloproteinase is identified by determining the presence or absence of a detectable or measurable manifestation of a signal element bound to the target antibody.

The Office Action cites U.S. Patent No. 5,736,341 to Sorsa, et al. as anticipating original independent claim 46 under 35 U.S.C. § 102(b). As noted in Applicants' previous response, Sorsa, et al. is specific to the use of a saliva sample, a mouthrinse sample, or a sample of gingival crevicular fluid (GCF) to diagnose whether or not a patient has periodontal disease. However, this is not a "chronic wound" as would be understood to one of ordinary skill in the art, e.g., an open cutaneous wound, burn wound, neuropathic ulcer, pressure sore, venous stasis ulcer, or diabetic ulcer.

In any event, Applicants respectfully submit that Sorsa, et al. also fails to disclose other limitations of independent claim 62. For example, claim 62 requires the selection of a tissue inhibitor (TIMP) that inhibits the activation or activity of the metalloproteinase based on the metalloproteinase identified. As described in the present specification, chronic wounds are characterized by an increase in the activity of MMPs, which are

responsible for the continued degradation of newly formed basal extracellular matrix (ECM). The stable formation of the ECM marks a committed entry into the healing process; however, constant ECM turnover results in an inability of the chronic wound to heal. Under normal circumstances, MMPs are prevented from destroying the wound bed by the action of tissue inhibitors of metalloproteinases (TIMPs). In chronic wounds, however, the ratio of MMP to TIMP is high, such that most of the MMPs are uninhibited. In fact, with elevated proteinase enzyme levels, the TIMP molecules themselves can be hydrolyzed. (Appl., pp. 1-3). As such, chronic wounds may be treated with inhibitory agents. Unfortunately, no naturally occurring TIMP molecule is known that inhibits all types of MMPs. TIMPs instead form inhibitory complexes with only a specific subset of MMPs. Thus, for therapeutic purposes, it is desirable to specifically identify which proteinase enzyme is present in the chronic wound. Further, because the levels of the proteinase enzymes are constantly in flux within a chronic wound, it is also desirable to identify the proteinase enzyme in the *current* condition of the chronic wound. (Appl., pp. 1-3).

The present inventors have thus discovered that the claimed rapid and accurate detection method allows for the immediate selection of a tissue inhibitor that is specific for the identified metalloproteinase. Advantageously, the inhibitory agent may be used to treat the *current* condition of the chronic wound, without having to wait several days for the result. Sorsa, et al. simply does not disclose a method in which such a tissue inhibitor (TIMP) is selected based on the identified metalloproteinase, as recited in independent claim 62. For at least these reasons, Applicants respectfully submit that the present claims patentably define over Sorsa, et al.

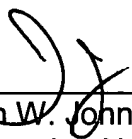
Previous independent claim 46 was also rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,143,506 to Golub, et al. However, Golub, et al. suffers from the same deficiencies noted above with respect to Sorsa, et al. For at least this reason, Applicants respectfully submit that the present claims patentably define over Golub, et al.

As such, at least for the reasons set forth herein, Applicants respectfully submit that the present application is in complete condition for allowance and favorable action, is therefore requested. Examiner Swope is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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